PHARMAC
Pharmaceutical Management Agency

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21 September 2020

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF ANAESTHETIC MACHINES, INVASIVE VENTILATION DEVICES, NEONATAL CARE DEVICES AND CRITICAL CARE PATIENT MONITORING DEVICES

PHARMAC invites proposals for the supply of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices to New Zealand DHB hospitals (and their associated community settings).

This request for proposals (**RFP**) letter incorporates the following schedules:

- Schedule 1 sets out the background to the RFP and the range of products included and types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 specifies the information and evidence you need to include in your proposal;
- Schedule 4 and Attachments 1, 3, 4 and 5 contain the forms in which you are to provide the details of your proposal; and
- Attachment 2 contains the PHARMAC standard terms and conditions to list medical devices on the Pharmaceutical Schedule.

All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than **4pm 20 November 2020.**

If you have any questions about this RFP, please post these on GETS.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

Schedule 1: Products, background to RFP and types of proposals sought

1. **Products**

PHARMAC is interested in considering proposals from suppliers of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices, for use in DHB Hospitals and their associated community settings (**DHB Hospitals**), that includes:

- anaesthetic machines, spare parts and consumables;
- invasive ventilators, spare parts and consumables; and
- invasive ventilators for neonatal care, spare parts and consumables; and
- neonatal care devices, spare parts and consumables; and
- critical care patient monitoring devices, spare parts and consumables.

The full scope of the RFP is outlined in Schedule 1, clause 5(a) below.

2. **RFP background and impact**

PHARMAC is taking a phased approach to its activity in medical devices. The Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices category is the latest category of medical devices that PHARMAC has commenced procurement activity in.

PHARMAC intends to establish national listing agreements (**National Contracts**) with suppliers to secure the supply of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices used by DHB Hospitals. It is expected that Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices, subject to a National Contract, will be listed in Section H, Part III of the Pharmaceutical Schedule. The National Contracts would not be exclusive of other suppliers, and it is likely that multiple suppliers of equivalent Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices will be listed, where appropriate.

DHBs would be able to purchase Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices under the National Contracts on the terms and conditions resulting from this RFP process. In some circumstances, resulting National Contracts may include provision for PHARMAC in conjunction with DHB Hospitals to seek proposals from and initiate limited negotiation with suppliers, for example where a DHB is replacing a fleet of devices or otherwise purchasing a significant volume of devices at one time.

There may be some devices and/or consumables associated with, but not exclusive to, Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices that are already listed in Part III Section H of the Pharmaceutical Schedule as the result of previous contracting activity. Suppliers who currently have devices and/ or consumables associated with Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices listed in Part III of Section H of the Pharmaceutical Schedule under other categories may submit additional proposals via this RFP that could result in an

amendment to their current agreement. Please note, however, that PHARMAC is unlikely to accept any price increases via a proposal under this RFP for those existing listed devices and/or consumables.

3. **Expected outcome of the RFP**

(a) PHARMAC intends to establish National Contracts with suppliers in the Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices category to:

i. list a range of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices available for use by DHB Hospitals in Part III of Section H of the Pharmaceutical Schedule;

ii. secure future supply of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices for DHB Hospitals at competitive prices;

iii. ensure access to an appropriate level of clinical support, and education, training and associated materials, for relevant DHB Hospital health professionals;

iv. ensure access to an appropriate level of technical support and training for Clinical Engineers and other relevant DHB Hospital personnel;

v. engage and establish relationships with new and current suppliers of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices; and

vi. move commercial arrangements for Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices into a national framework administered by PHARMAC, to create better health outcomes for patients within the funding available to DHB Hospitals.

(b) This RFP is the only process PHARMAC expects to run prior to negotiation of National Contracts with suppliers, to determine whether the Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices are contracted for and listed in the Pharmaceutical Schedule. Limited negotiations may be initiated by PHARMAC in conjunction with DHB Hospitals following completion of any National Contracts, for example where a DHB Hospital is looking to a replace a full fleet of devices or otherwise purchase a significant volume of devices at one time.

(c) PHARMAC recognises that the use of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices touches a wide group of patients and health professionals therefore, in the event a National Contract is entered into with a supplier, as an outcome of this RFP process, and the Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices are listed in Part III of Section H of the Pharmaceutical Schedule:

i. the listing shall be non-exclusive and will include pricing and details of the Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices;

ii. it will be discretionary for DHB Hospitals to purchase those Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices from the supplier, however where they do, DHB Hospitals will be expected to purchase the Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices under the PHARMAC National Contract listing terms and conditions;

iii. it is anticipated that multiple suppliers of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices will be listed, where appropriate; and

iv. the resultant National Contract will be between the supplier and PHARMAC for DHBs to be able to purchase under the National Contract, effective from the listing date, and DHBs will not be required to individually approve the National Contract for it to come into effect.

4. **Types of proposals sought**

(a) PHARMAC is willing to consider the following types of proposals:

i. proposals for Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices as set out in Schedule 1, clause 5(a) of this RFP;

ii. single pricing option Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices ; and

iii. additional pricing options like Tiered pricing, loan pricing and leasing options.

Please note that complex additional pricing models that would pose a significant administrative burden to PHARMAC or DHB Hospitals are unlikely to be progressed.

(b) Proposals must meet all the mandatory information and evidence requirements as set out in Schedule 3 of this RFP.

(c) Proposed products are expected to be priced as <u>'Free-into-Store'.</u> If this is not possible, then proposals must clearly outline the application of freight charges and associated costs to DHB Hospitals.

(d) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices during the life of the National Contract, and that if agreed between the parties, the changed or upgraded product would be made available to DHB Hospitals within a reasonable timeframe.

(e) PHARMAC is not willing to consider proposals for cross-category bundles of products.

(f) PHARMAC is not willing to consider out of scope products as set out in Schedule 1, clause 5(b) of this RFP.

(g) Suppliers wishing to submit proposals for the supply of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices to DHB Hospitals MUST submit proposals with pricing to be

published on the Pharmaceutical Schedule. Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

5. **Scope of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care and Critical Care Patient Monitoring Devices Category**

(a) In scope

PHARMAC is willing to consider proposals for Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices for listing in Part III of Section H of the Pharmaceutical Schedule for use by DHB Hospitals; and the following products are considered **'in scope'** of this RFP:

i. Anaesthetic machines, spare parts and consumables including but not limited to:

- workstations
- integrated patient monitoring gas monitoring
- consumables currently not listed in Section H, Part III of the Pharmaceutical Schedule as a result of contracts entered into following the Non-invasive ventilation equipment, oxygen concentrators, respiratory gas humidifiers and associated products RFP (**Non-invasive Ventilation RFP**) that PHARMAC has previously run.
- **EXCLUDING Vaporisers (see clause 5(c below).**

ii. Invasive ventilators, spare parts and consumables including but not limited to:

- transport ventilators
- unit based ventilators
- consumables currently not listed in Section H, Part III of the Pharmaceutical Schedule as a result of contracts entered into following the Non-invasive Ventilation RFP that PHARMAC has previously run. https://www.pharmac.govt.nz/hospital-devices/categories/ventilation/

iii. Invasive Ventilators for Neonatal care, spare parts and consumables including but not limited to:

- transport ventilators
- unit based ventilators
- consumables currently not listed in Section H, Part III of the Pharmaceutical Schedule as a result of contracts entered into following the Non-invasive Ventilation RFP that PHARMAC has previously run.

iv. Open and closed incubators for neonatal care, spare parts and consumables including but not limited to:

- Open incubators
- Closed incubators
- Transport incubators
- consumables currently not listed in Section H, Part III of the Pharmaceutical Schedule as a result of contracts entered into following the Non-invasive Ventilation RFP that PHARMAC has previously run.

v. Jaundice management devices for neonatal care, spare parts and consumables including but not limited to:

- Handheld devices for jaundice management
- Phototherapy devices and accessories
- consumables currently not listed in Section H, Part III of the Pharmaceutical Schedule as a result of contracts entered into following the Non-invasive Ventilation RFP that PHARMAC has previously run.

vi. Critical care patient monitoring, spare parts and consumables including but not limited to:

- Critical care Patient monitoring systems
- Telemetry devices
- Connectivity systems to integrate patient monitoring to hospital network
- consumables currently not listed in Section H, Part III of the Pharmaceutical Schedule as a result of contracts entered into following the Non-invasive Ventilation RFP that PHARMAC has previously run.

(b) Out of scope

PHARMAC is not willing to consider proposals for any other products for this RFP, including but not limited to the following products as identified as **'out of scope'** for this RFP:

i. Non-invasive ventilation machines and associated products;

ii. Suction units and other products used in respiratory and airway suctioning;

iii. Anaesthesia small equipment and consumables;

iv. Patient assessment, monitoring and treatment equipment; included in PHARMAC 2018 Multi-category patient assessment, monitoring and treatment and consumables RFP.

v. Volatile agents previous included in PHARMAC Pharmaceutical Schedule Section H, Part II – Hospital Pharmaceuticals; and

vi. Products not used with Anaesthetic Machines, Invasive Ventilation Devices, Neonatal care devices and Critical care Patient Monitoring devices.

(c) **ADDITIONAL INFORMATION**

PHARMAC is also requesting additional information regarding vaporisers currently supplied to DHB Hospitals. Please refer to the following attached documents for questions related to the information we are seeking on vaporisers:

I. Attachment 1 Spreadsheet for Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices Schedule 4 Proposal form

Schedule 2: RFP process

PHARMAC expects to follow the process set out below in the sequence indicated.

1. **Submission**

(a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

(b) All proposals must be submitted by a single submitter. Submitters may have joint commercial arrangements with other suppliers and these can be combined into a single submission.

(c) All proposals must be submitted to PHARMAC via GETS no later than **4pm** (New Zealand time) on **20 November 2020** Late proposals will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

(d) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.

(e) If you have any enquiries about this RFP, you should submit them via GETS (www.gets.govt.nz).

2. **Evaluation**

(a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal(s).

(b) The Evaluation Committee will evaluate proposals in light of PHARMAC's statutory objective, which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so, the Evaluation Committee will be guided by the Factors for Consideration (**FFC**) that form part of PHARMAC's current Operating Policies and Procedures (**OPPs**), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. Please be aware of the FFC. More information on the FFC can be found at www.pharmac.health.nz/factors-for-consideration.

(c) The information considered during the evaluation process will be at the discretion of the Evaluation Committee however it will include:

(i) information and evidence provided by you in accordance with Schedules 1, 3, 4 and 5 of this RFP;

(ii) your ability to legally supply the proposed products to New Zealand DHB Hospitals;

(iii) your ability to provide the appropriate level of product management and support, including but not limited to:

(A) clinical training and education in the use and handling of products where applicable;

(B) technical support, where applicable;

(C) technical training, where applicable;

(D) information for patients, where applicable;

(E) transition support;

(iv) your ability to ensure continuity of supply to DHB Hospitals including but not limited to:

(A) stock management;

(B) supply chain;

(C) identification and management of key risks to continuity of supply;

(v) DHB Hospital usage and financial impact, where applicable;

(vi) other major markets for the proposed products, where applicable;

(vii) provision of reference sites, where applicable;

(viii) any advice received from relevant clinicians and/or DHB Hospital staff; and

(ix) any other matters that the Evaluation Committee considers to be relevant (provided that PHARMAC will notify such matters and allow an opportunity for submitters of proposals to address them).

(d) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.

(e) PHARMAC is not bound to select the lowest priced proposal or any proposal.

3. **PHARMAC may request further information**

(a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to) detailed information about your company structure, credit status and any other relevant company information.

(b) If PHARMAC requests further information from or about you, it is not obliged to request the same or any other information from or about any other party provided that, in PHARMAC's judgment, this would not be unfair to any other party.

4. **Negotiation**

(a) PHARMAC may negotiate with the submitter(s) of one or more preferred proposals; in the latter case, whether or not the acceptance of either supplier's proposal would exclude acceptance of the other proposal.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions to list medical devices on the Pharmaceutical Schedule, which are available as a download (Attachment 2) from GETS, will apply.

(c) You **must** complete and submit Attachment 3 of this RFP as part of your proposal by declaring that you have read and understood PHARMAC's standard terms and conditions for the supply of medical devices, and where you disagree with any of the standard terms and conditions, include comments about the terms and conditions you would seek to amend during any negotiation.

(d) PHARMAC may negotiate and enter into a provisional National Contract with a preferred supplier(s) on whatever special terms, in addition to PHARMAC's standard terms and conditions, PHARMAC considers appropriate. For instance, PHARMAC may include special terms in a provisional National Contract which enable PHARMAC in conjunction with a DHB Hospital to seek proposals from and initiate limited negotiations with suppliers in respect of large-scale device purchases, for example where a DHB is replacing a fleet of devices or otherwise purchasing a significant volume of devices at one time.

(e) If PHARMAC and the supplier(s) are unable to reach a provisional National Contract within what PHARMAC considers to be a reasonable time, PHARMAC may terminate those negotiations and negotiate with a different supplier(s).

5. Consultation and approval

(a) Any provisional National Contract will be conditional on consultation with suppliers and other interested parties, to the extent PHARMAC considers consultation to be necessary or appropriate, and on Board approval (or approval by the Board's delegate acting under delegated authority).

(b) PHARMAC will not consider any counter-offers received during consultation.

(c) The provisional National Contract and responses to consultation will be considered by PHARMAC's Board (or by the Board's delegate acting under delegated authority) in accordance with the FFC in PHARMAC's then current OPPs.

(d) If the Board or its delegate does not approve the provisional National Contract, then PHARMAC may initiate negotiations for a provisional National Contract with any other supplier(s).

(e) The RFP process will be complete once PHARMAC has notified suppliers of either:

(i) the Board's or its delegate's decision to accept a negotiated National Contract; or

(ii) the termination of the RFP process.

6. Miscellaneous

(a) PHARMAC reserves the right, having regard to probity principles:

(i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that it notifies suppliers affected by those changes;

(ii) not to accept any proposal;

(iii) to seek clarification of any proposal;

(iv) to meet with any supplier in relation to its proposal;

(v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;

(vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional National Contract is entered into) it becomes apparent to PHARMAC that further consultation is appropriate or required we may suspend the RFP process in order to consult. In this situation we may ask you to adapt and resubmit your proposal in light of consultation, or alternatively we may request that new proposals be submitted;

(vii) to terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms PHARMAC thinks fit; and

(viii) to re-advertise for proposals.

(b) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such time as a provisional National Contract is accepted by PHARMAC's Board or the Board's delegate.

(c) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operation unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs, or advisors to PHARMAC, with a view to influencing the outcome of this RFP process.

(d) You must pay your own costs for preparing and submitting your proposal.

(e) You must limit the information provided to that which is requested in Schedule 3 and 4 and Attachments 1, 3, 4 and 5, and provide it succinctly and clearly. Please do not provide brochures or additional information (e.g. PEHNZ forms and presentations) unless specifically requested to do so in this RFP document.

(f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP document.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal care devices and Critical care Patient Monitoring by

PHARMAC's apparent acceptance, and instead a separate agreement needs to be negotiated.

(i) PHARMAC is not liable in any way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by you or any other person in relation to this RFP.

(j) It is possible that more than one supplier may be awarded a National Contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices or restricts the terms that may be agreed with any other supplier.

(k) PHARMAC will consider your proposal and information exchanged between the parties in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs ("**Confidential Information"**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:

(i) pursuant to the Official Information Act 1982; or

(ii) in the course of consultation on a provisional National Contract entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board of that National Contract; or

(iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.

PHARMAC may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for PHARMAC to decide, in its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that PHARMAC shall act in good faith in disclosing any Confidential Information.

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the PHARMAC internal Evaluation Committee evaluating proposals from December 2020;

(ii) negotiating with submitter(s) of one or more preferred proposals March 2021;

(iii) consulting on any provisional National Contracts from May 2021; and

(iv) PHARMAC's Board, or the Board's delegate, considering any provisional National Contracts from July 2021

provided that the above time frames are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is July 2021

8. **Governing Law**

The RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

Schedule 3: Information and evidence to be included in your proposal

Please include the following information and evidence in your proposal. Proposals that do not include mandatory information and evidence will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

Document	Evidence / Information
Attachment 1: **Anaesthetic Machines, Invasive Ventilation Devices, Neonatal care devices and Critical care Patient Monitoring Devices product detail**	You **must** complete all fields in Attachment 1 for each proposed product. If you consider a field not applicable you must state "NA".
WAND	You **must** be able to legally supply your proposed products to New Zealand DHB Hospitals as evidenced by WAND registration number. Please **do not** provide WAND documents. Where WAND is not applicable to a proposed product you **must** state the reason why it is not applicable.
International compliance	You **must** provide evidence of international compliance certification. The name of the certifying body and certificate number must be included in Attachment 1 for each proposed product and you **must** attach a copy of all relevant certificates.
GS1 (GTIN) and UNSPSC	It is desirable that you provide GTIN and UNSPSC codes for each proposed product at the time of submitting your proposal. Please note that PHARMAC's standard terms and conditions require provision of GTIN numbers, if requested by PHARMAC or a DHB, within six months of the request.
DHB usage data	If you are currently supplying a proposed product to any DHB Hospital, you **must** provide combined volume and cost information for all DHB Hospitals for the period 1 July 2015 to 30 June 2020 for all line items submitted in **Attachment 1**. You **must** also include any sales to DHB Hospitals (by DHB) via logistics providers separate from the DHB data.
Non-DHB reference sites	If you **are not** currently supplying a proposed Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices product to any DHB Hospital, you **must** provide three clinical reference sites for that product. It is desirable that the clinical reference sites you provide use the proposed Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring

Document	Evidence / Information
	Devices Monitoring products in similar clinical settings as DHB Hospitals would use them.
Attachment 3: **Acceptance of PHARMAC's standard terms and conditions**	You **must** complete, sign and date the declaration set out in Attachment 3. You **must** indicate whether you agree or disagree with PHARMAC's standard terms and conditions for medical devices for your proposed products. If you do not agree with any of PHARMAC's standard terms and conditions for medical devices for your proposed products you **must** provide detailed comment, including any proposed alternative clauses and justification, in Table 1 of Attachment 3. If you would like PHARMAC to consider any other terms and conditions that are not included in PHARMAC's standard terms and conditions, you **must** provide details and justification in Table 2 of Attachment 3.
Attachment 4: **Document and information checklist**	You **must** complete the document and information checklist set out in Attachment 4. You **must** note any additional attachments not specifically listed in the box provided in Attachment 4.
Attachment 5: **Financial analysis of your proposal**	If any of your proposed products are currently supplied to DHB Hospitals (contracted and non-contracted) you **must** provide a detailed financial impact analysis of your proposal for each DHB based on recent usage; to be **attached** as an Excel spreadsheet. A preferred format is included in Attachment 5. You may provide your financial analysis in an alternative format provided it is in Excel by line item and includes the following for each DHB and each proposed product: (a) the product description, code and brand and unit of measure details; (b) your current Price per unit of measure (as at 1 July 2020) offered to each DHB; (c) your proposed price per unit of measure (as included in Attachment 1); (d) DHB Hospital sales volume and value (including via logistics providers) for 1 July 2015 to 30 June 2020. (e) projected annual cost to each DHB at current price paid by the DHB *current price paid by the DHB x DHB historical 12 months sales volume* (f) projected annual cost to each DHB at proposed price (g) *proposed price x DHB historical 12 months sales volume* projected financial impact of your proposal **for each DHB**

Document	Evidence / Information
	projected annual cost at proposed price – projected annual cost at current price
Schedule 4: **Proposal form**	You **must** complete all sections of Schedule 4. If you consider a section to be not applicable, you **must** state "NA". The response you provide in each section **must** be comprehensive and relevant to the information that has been requested, and you **must** include relevant attachments.

Schedule 4: Proposal form

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
c/- Ruben Kunst-Sopacua
Device Category Manager

By electronic transfer using GETS **(www.gets.govt.nz)**

Dear Sir/Madam

Proposal for the supply of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices

In response to your request for proposals (**RFP**) dated 21 September 2020 we put forward the following proposal in respect of Anaesthetic Machines, Invasive Ventilation Devices, Neonatal Care Devices and Critical Care Patient Monitoring Devices.

Please refer to Schedule 3 for information and evidence to be included in your proposal. You must also include information as outlined Attachments 1,3, 4 and 5 as part of your proposal.

Set out below is further information in support of our proposal.

(a) Company details	
Full legal trading name in New Zealand	
Address	
Phone	
Email	
Facsimile	
(b) Contact person (s) for this RFP	
Name, Position	
Phone	
Mobile	
Email	

(c) Executive summary	
Proposal summary Include: • overview of products and services • benefits to DHB Hospitals of this proposal • why PHARMAC should accept this proposal	**Maximum 500 words**

(d) Information about our company, contracts and markets	
Company information	
Type of entity (legal status) Eg, a New Zealand registered limited liability company	
City and country of residence of our company	
Information about company size, structure and annual turnover Include sales/product support staff relevant to this RFP. **Attach** Organisational Chart.	
Total number of New Zealand based staff Include FTE for each section (eg. 5 FTE sale/product support, 4 FTE logistics, 3 FTE corporate and administration)	
Established locations within New Zealand Include function of each location (eg. head office, warehouse).	
Company ownership State ownership (eg. public ownership) Include: • any parent companies and relationships • names and percentage shareholdings of the major shareholders and directors	

Evidence of financial stability and ability to cover financial liabilities Include: • how you would cover your financial liabilities in the event of a major failure to supply (eg. a recall) • information about your financial stability (eg. annual turnover, guarantor companies) **Attach** supporting evidence (eg. annual financial report, Companies Register financial statement, insurance certificate, bank letter).	
Contracts and markets	
Current contracts and standing agreements in place with DHB Hospitals or organisations acting on their behalf Include all DHB contracts, not just those relevant to this RFP. For each provide: • parties to the agreement • contract reference number • type of agreement (national/regional/DHB specific) • range of products covered • expiry date • other relevant information (eg. now standing agreement after contract expiry) Can be provided as an attachment, note name of attachment in response column.	
Products not included Include any Anaesthetic Machines, Invasive Ventilation Devices, Neonatal care devices and Critical care Patient Monitoring devices currently supplied to DHB Hospitals (contracted or not contracted) that are not included in this proposal and the reason for this.	
Healthcare customers in New Zealand Include DHB Hospital and private healthcare organisations.	
Information on other major markets for proposed product ranges. For each product range include: • type of market (eg. Private hospital, public hospital)	***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are* ***not*** *currently purchasing.*

• any contracts held • annual revenue • any other relevant information	
Information about clinical reference sites Provide information about each reference site included in Attachment 1 including the location and relevant clinical settings in which the product is used (eg. Inpatient care, outpatient clinics, home use).	***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are* ***not*** *currently purchasing.*
Other relevant company and market information	

(e) Information about our ability to manage and support our proposed products		
Customer support hours Include: • standard support hours (NZ time) for customer support and orders • any 24/7 troubleshooting support relevant to the proposed products		
Product support staff Include information about technical skills, experience and qualifications of the staff that would be involved in supporting the proposed products (including those providing training and education).		
Training and education Include an overview of the training and education that would be regularly provided to DHB Hospitals for the proposed products including: • frequency • location • format • content • staff groups (eg. hospital, community) • other relevant information		
Training and education materials	For DHB Hospital staff	For patients where applicable

Include training and education materials that would be provided to DHB Hospitals purchasing the proposed products.		
Transition support Include an outline of the support that would be provided to DHB Hospitals transitioning to the proposed products. **Attach** a detailed transition plan setting out the transition steps, roles and responsibilities and timeframes. Note name of attachment in response column.		
Complaints management processes Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes.		
Other relevant information about ability to support the proposed products.		

(f) Information about our compliance with regulations and standards			
Quality Management System(s) certification for your company **If Yes, attach evidence** Include relevant section(s) of standard where certification is not for full standard.	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]
Quality Management Systems(s) certification for manufacturer(s) **If Yes, attach evidence** Include: • manufacturer's name • relevant section(s) of standard where certification is not for full standard	ISO 9001	ISO 13485	Other
Other relevant standards for the proposed products List any other standards that are relevant to the proposed products including but not limited to:	Standard	Compliance	Evidence

• AS/NZ standards • ISO standards • IEC standards Describe the extent of compliance with the listed standard and the product range the standard applies to. **Attach** evidence of compliance where available.			
Permit to supply the products to New Zealand DHB Hospitals Include: • a statement confirming that you have all the necessary rights and permits to supply the products and associated services to New Zealand DHB Hospitals. The relevant permits and rights may vary between products. Permits and rights include, but are not limited to, distribution rights and New Zealand legislative requirements for specific types of products, or • information about process and expected timeframe for obtaining the necessary rights and permits to supply the products and associated services to New Zealand DHB Hospitals.			

(g) Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB Hospitals	
Stock Management	
Minimum shelf life on delivery Include for each product range the minimum shelf life on delivery to a DHB Hospital.	
Stock holding within New Zealand Include any relevant information about how you would set and manage your stock levels in New Zealand for the proposed products.	
Warehouse location(s) within New Zealand Include if warehouse owned by company or owned by a logistics provider.	
Recall management Include how a major recall of a proposed product(s) would be managed.	
Supply Chain	

Company role in supply chain	Manufacturer	Distributor
	[Yes/No]	[Yes/No]
Distribution agreement(s) overview Include exclusivity, expiry date, termination notice period.	***NB.*** *Not required if you are the manufacturer and distributor of all proposed products.*	
Manufacture to delivery For each product range, describe supply chain from start of manufacture to delivery to DHB Hospitals or DHB Hospital nominated locations (eg. home delivery), including: • all supply chain steps • who is involved • timeframes		
Potential supply issues and response to unexpected increase in demand		
Key supply continuity risks and mitigations For each product range include the key risks to continuity of supply to DHB Hospitals and the steps that will be taken to mitigate these risks.		
Response to unexpected increase in demand Include: • any access to alternative international supply and timeframes • communication with DHB Hospitals • communication with PHARMAC • how stock is prioritised • other relevant information		

(h) Financial analysis of our proposal	
Financial impact Include overview of how proposed pricing compares to that currently offered to DHB Hospitals. **Attach** detail in Excel format. (preferred format is included in Attachment 5; alternative formats may be submitted provided the detail set out in Schedule 3 is included).	***NB.*** *Only required if the proposed products are currently supplied to DHB Hospitals*

(i) Information about equipment	
Equipment details Provide overview information relating to proposed terms for supplying equipment to DHBs in addition to details provided in Attachment 1, including the range of procurement options being proposed (eg. outright purchase, rent, loan, lease, rent-to-buy). In a separate **attachment**, include, for each procurement option: • the applicable equipment product codes • delivery, receipt, installation and acceptance procedures • details of risk and liability during key exchange activity points • details of any consignment arrangements • details of any termination terms and conditions • any differences between current arrangements with DHB Hospitals and proposed arrangements • product support, training and education • charge for any non-purchase options, if any (eg. monthly rental charge, free of charge loan) • fleet management responsibilities for any non-purchase options Please note the name of the attachment in the adjacent box under your overview as well as in the checklist in Attachment 4. Where you have non-purchase equipment options currently in place with any DHB Hospital please include the financial analysis, by DHB Hospital, of any proposed non-purchase options in **Attachment 5**. Pricing for outright purchase options is to be included in **Attachment 1.**	***NB.*** *Only required if the proposed products include equipment*

Warranties, servicing and calibration Provide information relating to proposed warranty, servicing and calibration terms for equipment in addition to details provide in Attachment 1. Include: • useful life of equipment • details of replacement and repairs policy • overview of warranty coverage, including warranty terms for repairs and spare parts • cost for all maintenance and calibration services within the warranty period and following expiry of warranty period (eg. hourly labour rate for repairs outside of warranty, maintenance servicing costs per device per year, any freight charges or travel and accommodation costs) • training of DHB staff (eg. clinical engineers), and any associated costs • any differences between current arrangements with DHB Hospitals and proposed arrangements If the detail varies according to the type of equipment or procurement option, please note this here and include the relevant information with the attachment in the Equipment details section above.	
Operating and maintenance manuals Include an overview of the content of operating manuals, instructions and guides for use by clinical and technical personnel. **Do not** include copies of full equipment operating or maintenance manuals.	

(j) Other relevant information	
Pricing information Include any information related to pricing provided in Attachment 1, including any related conditions or proposed terms.	

Equipment charges Include any charges for loan units, loan models & rental options, maintenance costs, service contracts relating to pricing provided in Attachment 1.	
Additional charges Include any charges not included in pricing provided in Attachment 1 and associated conditions.	
Additional options Include any additional proposals or suggestions not expressly identified in this RFP that you would like PHARMAC to consider as part of this proposal. Also refer to Attachment 3.	
Other information Include any other information that you would like PHARMAC to consider when evaluating this proposal.	